REMARKS

Applicant wishes to thank the Examiner for the attention accorded to the instant application, and respectfully requests reconsideration of the application as amended.

Formal Matters

Claims 1-21 are currently pending in the application. Independent Claims 1 and 13 are amended to clarify the features and limitations of the claims. Support for the amendments is found, for example, at Page 27, Lines 5-10, and Page 33, Line 16 to Page 36, Line 22 of the specification. No new matter has been added.

Rejection of Claims Under 35 U.S.C. §103

The Examiner has rejected Claims 1-5 and 9-15 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,755,715 to Stern et al., (hereinafter "Stern") in view of U.S. Patent No. 5,405,337 to Maynard (hereinafter "Maynard") and in further view of U.S. Patent No. 6,334,093 More (hereinafter "More"). This rejection should be withdrawn based on the comments and remarks herein.

Among the problems recognized and solved by the present invention is the need to avoid having to use separate temperature monitors or temperature sensors for an endoscope type medical instrument and to consequently reduce the overall cost of the medical instrument and medical procedure. In light of the above need, Applicant's inventive solution contemplates a novel method for measuring the temperature adjacent a position sensor of the medical instrument, by means of determining a resistance value at the position sensor. In such a manner, the instantaneous temperature value of an ablation electrode adjacent the position sensor can be obtained, to facilitate a physician to adjust the ablating operation. Such a practice offers direct safety benefit to patients.

Accordingly, Claim 1 recites a method for measuring temperature at a site within a patient during a medical procedure, the method comprising: *inter alia*, providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor; placing the medical device within the patient and positioning the position sensor at the site; determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system; and providing a temperature measurement signal <u>to the position sensor</u>; measuring voltage <u>at the position sensor</u>; determining a resistance value <u>at the position sensor</u> based on thc temperature measurement signal <u>provided to the position sensor</u> and the voltage <u>at the position sensor</u>; and determining a temperature value <u>at the position sensor</u> based on the resistance value <u>at the position sensor</u>.

Accordingly, Claim 13 recites a method for adjusting for temperature sensitivity of a medical device having a position sensor, the method comprising: *inter alia*, providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor; determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system; measuring voltage <u>at the position sensor</u>; determining a resistance value <u>at the position sensor based on</u> the measured voltage <u>at the position sensor</u>; determining a temperature value <u>at the position sensor</u> based on the resistance value; and determining a sensitivity <u>at the position sensor</u> based on the temperature value.

The present invention, as recited by both Claims 1 and 13, articulates the correlation between the operational steps <u>associated with the position sensor</u> and the resultant temperature

obtained at a site within a patient. For example, both Claim 1 and Claim 13 recite determining a temperature value at the position sensor based on the resistance value at the position sensor.

Turning to the prior art, Stern is directed to an apparatus for ablating heart tissue using energy emitted from an energy source. Specifically, Stern discloses a temperature sensor (30), in the form of a bead thermistor, carried by the distal tip (16) of the catheter (14) for directly measuring a temperature (*see*, Col. 6, Lines 15-17):

> "The temperature control signal $T_{CONTROL}$ input is based upon the actual instantaneous temperature conditions sensed $T_{M(t)}$ by the sensing element 30."

Thus, Stern only teaches the application of a traditional temperature sensor for measuring a temperature at a site within a patient. Also, the Examiner has conceded that Stern does not specifically diselose the use of a position sensor (see, Page 3, Lines 4-5 of the Office Action). Accordingly, Stern fails to teach or fairly suggest the above operational steps associated with the position sensor, recited by Claims 1 and 13. For example, Stern at least fails to teach or suggest determining a temperature value at the position sensor based on the resistanee value at the position sensor.

The Examiner alleges, "Stern et al. disclose upon use of the system a voltage is measured at the site of interest and a temperature measurement signal is taken (col. 5, lines 10-64)" (*see*, Page 2, Lines 9-11 of Item 2 of the Office Action).

Applicant respect submits that, although Stern discloses measuring a voltage, Stern does not disclose the step of measuring voltage at the position sensor, especially in view of the following description of Stern (*see*, Col. 5, Lines 45-60):

> "The multiplier 60 receives … and an instantaneous voltage signal V(t) from an isolated voltage sensing transformer 64" and "The voltage sensing transformer 64 measures the instantaneous radio frequency voltage V(t) across body tissue between the ablation eleetrode 16 and the indifferent electrode 18".

The measuring of voltage as described by Stern is related to the radio frequency voltage applied to the ablation electrode, which cannot be reasonably interpreted as a disclosure for the step of measuring a voltage at the position sensor.

The Examiner also alleges, "Stern et al. disclose the temperature is determined based on an algorithm which includes a resistance value obtained (col. 5; col. 6, lines 1-35)" (*see*, Page 2, Lines 11-12 of Item 3 of the Office Action).

Applicant respectfully submits that, although Stern discloses measuring a resistance value, Stern does not disclose the step of <u>determining a resistance value at the position sensor based on the measured voltagc at the position sensor</u>, especially in view of the following description of Stern (*see*, Col. 6, Lines 20-22):

> "In the particular illustrated embodiment, the first processing stage 56 receives as $T_{CONTROL}$ the output resistance value of the thermistor 84 (in ohms). It divides this resistance value by the calibration value R_{CAL} to normalize the resistance value of the thermistor 34".

The processing of resistance value as described by Stern is related to a thermistor (which is not required by the present invention), which cannot be reasonably interpreted as a disclosure for the step of measuring a voltage at the position sensor.

The Examiner further alleges, "Stern et al. disclose thermal mapping teehniques employed to determine temperature curve coordinates" (*see*, Page 2, Lines 8-9 of Item 3 of the Office Action). However, Applicant respectfully submits that the alleged teaching of thermal mapping techniques in Stern still fails to provide any correlation between a position sensor and a temperature measured at a site within a patient.

In view of the deficiency of Stern, the Examiner has turned to Maynard for the alleged teaching of a position sensor. Maynard discloses a shape memory alloy (SMA) aetuator film used to control the steering of a tube-shaped medical device, such as a catheter. The

Examiner has relied on the disclosure at Col. 8, Lines 3-25 of Maynard for the alleged teaching of a position sensor (*see*, Page 3, Lines 7-9 of the Office Action).

> "That is, the SMA actuators 105, address decode 118 and control circuitry, including switch means 114, as well as positional sensors and sensors for measuring environmental parameters, are all integrally formed as a VLS1 circuit incorporated in a flexible polyimide sheet 100".

In this regard, Applicant respectfully submits that merely mentioning a positional sensor does not reasonably discloses the operational steps associated with the positional sensor. Maynard at best teaches that a traditional positional sensor can be integrated with the actuator. Furthermore, assuming the environmental parameter measured by the Maynard device includes temperature, as alleged by the Examiner, that does not mean the temperature is measured through a serial of operational steps associated with the positional sensor. Maynard actually indicates that a temperature sensor maybe further integrated with the actuator.

In other words, Maynard fails to teach or suggest the above distinguishing steps of Claims 1 and 13 over Stern. Specifically, Claim 1 recites providing a temperature measurement signal <u>to the position sensor</u>; measuring voltage <u>at the position sensor</u>; determining a resistance value <u>at the position sensor</u> based on the temperature measurement signal <u>provided to the position sensor</u> and the voltage <u>at the position sensor</u>; and determining a temperature value <u>at the position sensor</u> based on the resistanee value <u>at the position sensor</u>. Claim 13 recites measuring voltage <u>at the position sensor</u>; determining a resistance value <u>at the position sensor based on</u> the measured voltage <u>at the position sensor</u>; determining a temperature value <u>at the position sensor</u> based on the resistance value; and determining a sensitivity <u>at the position sensor</u> based on the temperature value.

In addition, the Examiner alleges, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a tissue heating and ablation system, similar to that disclosed by Stern et al., to include a film to be used with a steerable catheter,

similar to that disclosed by Maynard, to provide information regarding the location of the device while enabling the device to be accurately positioned at the target site" (*see*, Page 3, Lines 10-14 of the Office Action).

In this regard, Applicant respectfully submits that the hypothetical combination of the Stern arrangement and the Maynard arrangement would only result in a system wherein the temperature of a site is measured by a temperature sensor such as the thermistor (30) of Stern. Furthermore, the combined system may provide an operational environment similar to that of the present invention, but in no event does the combined system disclose the distinguishing steps of the present invention.

More is relied on for the alleged teaching of applying a resistance drift compensation factor. Without acquiescing the corrcetness of the Examiner's interpretation of More, Applicant respectfully submits that More does not remedy the underlying deficiencies of Stern and Maynard relative to independent Claims 1 and 13.

Thus, none of the cited references, namely Stern, Maynard and More, taken alone or in eombination, teach or fairly suggest the combination of steps recited by Claims 1 and 13, from which all other claims depend ultimately.

Accordingly, withdrawal of the rcjection of Claims 1-5 and 9-15 under 35 U.S.C. § 103(a) based on the hypothetical combination of Stern, Maynard and More is respectfully requested.

The Examiner has further rejected Claims 6-8 under 35 U.S.C. § 103(a) as allegedly unpatentable over Stern in view of Maynard, More and U.S. Patent No. 5, 833,608 to Acker (hereinafter "Acker"). This rejection should be withdrawn based on the comments and remarks herein.

Claim 1, from which Claims 6-8 depend, is discussed above. Stern, Maynard and More are discussed above relative to Claim 1.

Acker is relied on to allegedly teach the additional limitations recited by Claims 6-8, such as AC magnetie field and temperature measurement signal. Without acquiescing the correctness of the Examiner's interpretation of Acker, Applicant respectfully submits that Acker does not remedy the underlying deficiencies of Stern, Maynard and More relative to independent Claim 1.

Thus, the hypothetical combination of Stern, Maynard, More and Acker fails to teach or fairly suggest the combination of steps recited by Claim 1. Accordingly, withdrawal of the rejection of Claims 6-8 under 35 U.S.C. § 103(a) based on the hypothetical combination of Stern, Maynard, More and Acker is respectfully requested.

The Examiner has rejected Claims 16-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Stern in view of Maynard, More and U.S. Patent No. 5, 638,418 to Douglas et al., (hereinafter "Douglas"). This rejection should be withdrawn based on the comments and remarks herein.

Claim 13, from which Claims 16-21 depend, is discussed above. Stern, Maynard and More are discussed above relative to Claim 13.

Douglas is relied on to allegedly teach the additional limitations recited by Claims 16-21, such as applying a resistance drift factor to the resistance value. Without acquiescing the correctness of the Examiner's interpretation of Douglas, Applicant respectfully submits that Douglas does not remedy the underlying deficiencies of Stern, Maynard and More relative to independent Claim 13.

Thus, the hypothetical combination of Stern, Maynard, More and Douglas fails to teach or fairly suggest the combination of steps recited by Claim 13. Accordingly, withdrawal of the rejection of Claims 16-21 under 35 U.S.C. § 103(a) based on the combination of Stern, Maynard, More and Douglas is respectfully requested.

In view of the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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